

EXTERNAL DISCUSSION DRAFT
April, 2022

2. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

2.1. Permitted Uses: Business Associate agrees to not use or disclose PHI other than as permitted or required by this BAA, the Agreement or as permitted or required by Law.

2.2. Permitted Disclosures: Business Associate may use and disclose PHI for the proper management and administration of Business Associate; provided that with respect to any disclosures of PHI, such disclosures are Required by Law or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person agrees to notify the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached. Business Associate may, in accordance with the Privacy Rule, de-identify Covered Entity's PHI and further use and disclose such de-identified health information without regard to this BAA or HIPAA. Without limitation of the foregoing, Covered Entity acknowledges that, to the extent Business Associate is also a covered entity (as such term is defined by HIPAA), the legal structure of the Business Associate and its covered entity affiliates affords Business Associate the opportunity to be designated as a participant in an affiliated covered entity arrangement ("HIPAA Arrangement"). To the extent Business Associate is not a covered entity (as such term is defined by HIPAA), the Business Associate is a subsidiary, affiliate, and/or related organization of its covered entity affiliates. Business Associate represents and warrants that it has been designated as a participant in such HIPAA Arrangement or is a subsidiary, affiliate, and/or related organization of its covered entity affiliates. As such, Covered Entity agrees that Business Associate may use or disclose Covered Entity PHI, in compliance with the terms of this BAA, (i) to other participants in the HIPAA Arrangement or their business associates, or (ii) as a subsidiary, affiliate, and/or related organization of its covered entity affiliates.

2.3. Obligations of Business Associate.

2.3.1. Safeguards. Business Associate agrees to use appropriate physical, administrative and technical safeguards to prevent the use or disclosure of Covered Entity's PHI for any purpose other than those permitted by this BAA.

2.3.2. Agents and Subcontractors. In the event Business Associate engages any agent or Subcontractor to perform any Deliverables and discloses PHI to such agent or Subcontractor, Business Associate will require any such agent or Subcontractor to agree to the same restrictions and conditions required in this BAA that may be applicable to such agent or Subcontractor.

2.3.3. Inspection and Copies. Upon written request from the Covered Entity, Business Associate agrees to make PHI available to Individuals in accordance with 45 C.F.R. Section 164.524, governing access of Individuals to their PHI.

2.3.4. Amendments. Upon written request from the Covered Entity, Business Associate agrees to make PHI available for amendment and incorporate any amendments in

EXTERNAL DISCUSSION DRAFT
April, 2022

accordance with 45 C.F.R Section 164.526, governing amendments to PHI.

2.3.5. Accounting of Disclosures. Upon written request from the Covered Entity, Business Associate agrees to make any and all information available for the purpose of providing Individuals an accounting of disclosures of their PHI in accordance with 45 C.F.R. Section 164.528, governing accounting of disclosures of PHI.

2.3.6. Access to Books and Records. Business Associate agrees to make its internal practices, books and records related to the use and disclosure of Covered Entity PHI hereunder available to the Secretary of HHS for the purposes of determining Covered Entity's compliance with HIPAA.

2.3.7. Security Rule Obligations. Business Associate shall implement and maintain administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Covered Entity's electronic PHI in accordance with the Security Rule.

2.3.8. Breach Notification. Business Associate will report to Covered Entity, within a reasonable time period of discovery, any (i) breach of this BAA; or (ii) Breach as defined at the Breach Notification Rule (collectively "Incident") (a) any material breach of the Agreement ("material breach"); or (b) Breach as defined at 45 C.F.R. Part 164, Subpart D. Business Associate may supplement its initial report as information becomes available in order to identify:

- a. The nature of the material breach or Breach, including how such material breach or Breach was made;
- b. The PHI that was the target of the material breach, or the unsecured PHI involved in the Breach, including the types of identifiers involved and the likelihood of re-identification;
- c. If known, the identity of the person/entity who used or received the PHI;
- d. Whether PHI was actually acquired or viewed;
- e. What corrective action Business Associate took, if any;
- f. What Business Associate did to mitigate any risk or deleterious effect; and
- g. Such other information as Covered Entity may reasonably request.

2.3.9. Compliance with Law. At all times during the Term, Business Associate will comply with all applicable federal, state and local laws, rules and regulations pertaining to patient records and the confidentiality of patient information, including Covered Entity's PHI. To the extent Business Associate is to carry out Covered Entity's obligation under the Privacy Rule, Business Associate will comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of the obligation.

3. OBLIGATIONS OF COVERED ENTITY

3.1. Restrictions Requests and Confidential Communications. Covered Entity will notify

EXTERNAL DISCUSSION DRAFT
April, 2022

Business Associate of any agreement Covered Entity makes regarding any restriction or requirement for confidential communication with respect to the use or disclosure of PHI, to the extent that such restriction agreement or confidential communication requirement may affect Business Associate's use or disclosure of PHI.

3.2. Safeguards. Covered Entity will employ appropriate safeguards to maintain and ensure the confidentiality, privacy and security of PHI transmitted to Business Associate pursuant to this BAA and the Agreement, in accordance with the standards and requirements of HIPAA, the Privacy Rule and Security Rule, until such PHI is received by Business Associate;

3.3. Withdrawal of Consent. Covered Entity will inform Business Associate of any consent or authorization, including any changes in or withdrawal of any such consent or authorization, provided to the Covered Entity by an Individual that would affect Business Associate's use or disclosure of the PHI.

4. TERM AND TERMINATION

4.1. Term. This BAA shall commence of the Effective Date and remain in effect until terminated in accordance with Section 4.2

4.2. Termination.

4.2.1. This BAA will terminate automatically upon the termination or expiration of the Agreement.

4.2.2. Covered Entity may terminate this BAA or the Agreement, for Business Associate's material breach of this BAA, where such breach is not corrected to the reasonable satisfaction of the Covered Entity by Business Associate within thirty (30) days of receiving Covered Entity's notice of breach.

4.3. Effect of Termination. Upon termination of this BAA, Business Associate shall return or destroy all PHI received from or created or received on behalf of Covered Entity. In the event Business Associate determines that return or destruction is not feasible, Business Associate will extend the protections required in this BAA to the PHI and limit further uses and disclosures to only those purposes that make the return or destruction of the information infeasible.

5. MISCELLANEOUS

5.1. Regulatory References. A reference to HIPAA or the HITECH Act, or a section thereof, and its regulations and requirements means the provisions and section(s) in effect, as may be modified or amended, including by the issuance of regulations and guidance by HHS.

5.2. Amendment. Each party will cooperate reasonably to amend this BAA in the event that such amendment is necessary for Covered Entity and/or Business Associate to comply with any new final regulation or amendment to final regulation promulgated by HHS during the term of this BAA. Both parties agree that the provisions of HIPAA and the HITECH Act,

EXTERNAL DISCUSSION DRAFT
April, 2022

including any implementing regulations to be published by HHS, which apply to business associates, that are not otherwise addressed herein, and that are required to be incorporated into a HIPAA business associate agreement, are hereby incorporated into this BAA as if set forth in this BAA in their entirety and are effective as of the applicable compliance date.

5.3. Notices. Any notices to be delivered hereunder shall be delivered in accordance with the notice provision(s) of the applicable Agreement; provided, that a copy of any notice to Business Associate shall also be delivered to: DaVita Inc., 2000 16th St. 12th Floor, Denver, CO 80202, Attention: Privacy Office. Notice shall be in writing and shall be deemed effective when personally delivered or, if mailed, three (3) calendar days after the date deposited in the United States mail, first class, postage prepaid, to the addressee at its current business address.

5.4. Governing Law. All issues and questions concerning the validity, enforcement and interpretation of this BAA shall be governed by, and construed in accordance with, the laws of the state identified in the Agreement.

5.5. Joint Preparation. Each party: (i) has participated in the preparation of this BAA; (ii) has read and understands this BAA; and (iii) has been represented by counsel of its own choice in the negotiation and preparation of this BAA, and (iv) represents that this BAA is executed voluntarily and should not be construed against any party solely because such party drafted some or all of this document.

5.6. Severability. Whenever possible, each provision of this BAA shall be interpreted in such manner to be effective and valid under applicable law, but if any provision of this BAA is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision in any other jurisdiction, but this BAA will be reformed, construed, and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

5.7. Entire Agreement. This BAA supersedes any and all prior business associate agreements and understandings relating to its subject matter, whether oral or written between the parties.

5.8. Independent Contractor. Nothing in this BAA shall be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this BAA, or to create any partnership, joint venture, legal association, or other operating relationship other than that of independent contractors. The governing bodies of each party shall have exclusive control of the policies, management, assets, and affairs of their respective organization.

EXTERNAL DISCUSSION DRAFT
April, 2022

IN WITNESS WHEREOF, the parties hereto have caused this Business Associate Agreement to be executed and delivered as of the Effective Date.

COVERED ENTITY:

BY: _____

ITS: _____

DATE: _____

BUSINESS ASSOCIATE:

BY: _____

ITS: _____

DATE: _____

EXHIBIT E

EXTERNAL DISCUSSION DRAFT
April, 2022

BASIS FOR METRIC SELECTION

Clinical performance metrics selected for CIP are based on recognized practice guidelines, published clinical research, and other recognized sources that support these metrics as correlating with a positive impact on patient outcomes. These metrics also recognize specific contributions from physicians that influence clinical events and outcomes of patients. Nephrologists are responsible for initiating and completing the activities associated with each metric. As such, the performance metrics incentivize actions that are aligned with either better patient outcomes or better patient health-related quality of life based on nationally-endorsed quality measures, federal legislation, and/or existing DaVita clinical performance or program measures.

These metrics, as shown in the table below designed specifically for physicians who are caring for patients aligned to a DaVita value based arrangement and are either (a) prevalent CKD patients not on kidney replacement therapy, (b) CKD patients new to ESKD dialysis, or (c) prevalent ESKD patients. Each value-based care program has its own definitions regarding the patient attribution to that program and may not be inclusive of certain patient disease states (such as CKD) or moments in time (such as the patient's transition to ESKD).

Domain	Metric	Definition	Reference
Treatment of CKD	Controlling Blood Pressure	High CKD patients who had a diagnosis of hypertension and whose blood pressure ("BP") was adequately controlled (<140/90 mmHg) in most recent measure in a calendar year.	NQF Measure #0018, MIPS ²
	Appropriate ACEi/ARB Usage	CKD 4 patients diagnosed with hypertension and UACR >300 mg/g or UPCR > 0.3g prescribed ACEi or ARB within a calendar year and present in an active medication list during program eligibility.	NQF Measure #1662
Transition	Home Start	New ESKD patients whose first outpatient treatment is a home dialysis modality and who remains on a home dialysis modality for a period of not less than 90 days.	NQF Measure #2594 Optimal End-Stage Renal Disease (ESRD) Starts ⁵ and AAKH Executive Order ⁶
	AVF/AVG Only Start	New ESKD patients who experience a planned start of kidney replacement therapy by initiating outpatient in-center hemodialysis via an AVF or AVG without a CVC in place.	NQF Measure #2954 Optimal End-Stage Renal Disease (ESRD) Starts ⁵ and CMS ESRD Vascular Access TEP Summary Report, April 22-23, 2015 ⁷
	Outpatient (In-Center Hemodialysis) Start	New ESKD patients who experience a planned start of kidney replacement therapy by initiating outpatient-in-center hemodialysis without preceding inpatient dialysis treatment.	NQF Measure #2594 Optimal End-Stage Renal Disease (ESRD) Starts ⁵
	Transplant (CKD/ESKD)	CKD or ESKD patients whose kidney transplant stays healthy for at least 1 year, and up to 3 years.	Kidney Care Choice Model: Kidney Transplant Bonus (KTB)
Optimal	CVC Removal	ESKD patients who initiate outpatient dialysis with either an active CVC or an	MIPS Clinical Quality Measures #329 Adult

EXTERNAL DISCUSSION DRAFT
April, 2022

Domain	Metric	Definition	Reference
Dialysis		<p>inactive CVC, and have transitioned to any access other than CVC within 90 days and had the CVC removed.</p> <p>FOR ESKD ENROLLMENT (Chronic Special Needs Plan; Direct Contracting) PROGRAMS:</p> <p>ESKD patients who enroll with either an active CVC or an inactive CVC, and have transitioned to any access other than CVC within 180 days of enrollment with CVC removed.</p>	Kidney Disease: Catheter Use at Initiation of Hemodialysis ⁸ and #330 Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days ⁸
	Home Conversion	ESKD patients who transfer from ICHD to a Home Modality for a period of not less than 90 days.	Morfin <i>et al.</i> , ⁹ Bowman BT, ¹⁰ DaVita Home Metric ⁷

Controlling High Blood Pressure

The rationale for controlling high blood pressure to treat CKD is based on an abundance of data demonstrating the beneficial effects of treating hypertension to prevent and slow the onset of kidney disease and improve cardiovascular outcomes.^{21 22}

One out of every three Americans have hypertension or high blood pressure. Even with the availability of effective treatment options, approximately half (54%) of these people have their high blood pressure under control.³ Improvements in quality or better control of blood pressure as related to this measure could help significantly reduce the probability of serious and costly complications, including coronary artery disease, congestive heart failure, stroke, ruptured aortic aneurysm, kidney disease and retinopathy.

The American Society of Nephrology Quality Committee reviewed this measure and found it to have high validity based on importance, appropriateness, clinical evidence, clarity of specifications, and feasibility of implementation.¹

Appropriate Angiotensin Converting Enzyme Inhibitor (ACEi)/Angiotensin Receptor Blocker (ARB) Usage

The role of ACEi or ARB to treat hypertension and slow the progression of chronic kidney disease (CKD) in patients with albuminuria or proteinuria is well-established in the medical literature and is endorsed as a quality measure by the National Quality Forum.^{1, 2} Appropriate ACEi or ARB use in patients with albuminuria or proteinuria is supported by the Renal Physicians Association and considered a highly valid quality metric by the American Society of Nephrology Quality Committee.^{1, 2}

Use of ACEi or ARB to treat both diabetic and non-diabetic patients with severely increased albuminuria (UACR > 300 mg/g or 24 hour urine albumin > 300mg) or proteinuria (UPCR > 0.3g or 24 hour urine > 0.3g) is considered a 1B strong recommendation based on moderate quality evidence by the Kidney Disease: Improving Global Outcomes (KDIGO) Blood Pressure Work Group (3). ACEi or ARB therapy have been shown to reduce the risk of kidney failure and may reduce major cardiovascular events (3). The benefits of ACEi or ARB therapy may also benefit patients with diabetic CKD and severely increased albuminuria independent of blood pressure effect.²³

Table 2. Summary of selected evidence for ACEi or ARB effect versus placebo or standard care²⁴

EXTERNAL DISCUSSION DRAFT
April, 2022

Drug indication	Outcome	Results	Effect estimates	Evidence quality	Comment
ACEi	ESKD	Relative risk 0.60 (95% CI 0.39-0.93)	16 fewer events per 1000 patients	Moderate	Decreases ESKD incidence
ARB	ESKD	Relative risk 0.78 (95% CI 0.67-0.91)	49 fewer events per 1000 patients	Moderate	Decreases ESKD incidence

KDIGO makes a strong recommendation to treat with ACEI/ARB for patients with hypertension, diabetes, and CKD with moderately-severely increased albuminuria.²³⁻²⁶ However, the benefit of initiating or continuing ACEi or ARB is less certain for patients with stage 5 CKD, and must weighed against risks of hyperkalemia and accelerated progression to kidney failure.²³⁻²⁵ Thus, the metric is limited to patients with CKD stage 4 in the NCA CIP 3.0 program. For prevention of death or reduction in risk hospitalization, the effect of ACEi or ARB on CKD patient outcomes is less certain.²⁷

Transplant (CKD/ESKD)

Ample scientific research shows that preemptive transplant, with avoidance of dialysis altogether, is associated with lower mortality, lower cardiovascular risk, improved quality of life, less hospitalization, and lower costs.^{5, 14, 15} A functioning transplanted kidney does a better job of filtering wastes than dialysis.⁶ Additionally, transplant recipients have improved life expectancy compared to individuals on dialysis.⁶ These recommendations are echoed by international kidney organizations like the United Kingdom Renal Association, who recommend that preemptive kidney transplant should be the therapy of choice for patients with stage 5 CKD.⁵ The benefits of preemptive transplant also extend to post-transplant kidney outcomes, with the hazard ratio for 5-year graft loss of preemptive transplant versus 1-3 years of dialysis before transplant 0.75 (p<0.001).¹⁶

Kidney transplantation is widely viewed as the best treatment for most patients with ESRD, generally increasing survival and quality of life while reducing medical expenditures. However, in 2017 only 29.9% of prevalent ESRD patients in the U.S. had a functioning transplant and only 2.9% of incident patients received a preemptive transplant.²⁸

Home Dialysis, and AVF or AVG Only Starts

Home PD provides excellent survival, lower cost, improved quality of life, and, by virtue of CVC avoidance, nearly eliminates the risk of bloodstream infection associated with dialysis initiation.¹⁷ CVC use in hemodialysis is associated with the highest risk of bloodstream infections compared to AVF, AVG, or PD catheter use.^{5, 7} Home dialysis, and AVF or AVG starts as defined by the CIP model are characterized by CVC avoidance. Home dialysis and AVF or AVG starts are associated with lower mortality, lower cardiovascular risk, improved quality of life, less hospitalization, and lower costs.⁵ CVC-related infections and complications result in increased mortality, hospitalizations, and health care costs.⁵⁻⁷ Promotion of best practices and strategies to reduce dialysis-related bloodstream infections and their associated negative outcomes, and patient well-being is another specific objective of the AAKH Executive Order.⁶ A primary objective of AAKH is to promote home dialysis, including PD use, which is more convenient for patients, provides equal, if not better early survival, and lower the costs of delivering kidney replacement therapy.⁶

EXTERNAL DISCUSSION DRAFT
April, 2022

These distinct, but closely related, metrics all converge on clinical and economic benefit which are largely based on CVC avoidance, are consistent with the recommendations of NQF Quality Measure 2594 and the CMS ESRD Vascular Access Technical Expert Panel, which endorse CVC avoidance and promotion of AVF/AVG use to reduce infection risk and improve patient outcomes.^{5,7}

Outpatient (ICHD) Starts

Inpatient hemodialysis starts are often unplanned and associated with inadequate CKD preparation for ESKD. These “crash” starts are often associated with CVC use, with increased risk of infection.^{5,7} Mortality in the immediate post-hemodialysis transition period is extremely high, and is associated with inpatient versus outpatient HD initiation.¹⁸ Outpatient dialysis starts reflect adequate pre-ESKD care and this is associated with improved survival in the first 120 days of dialysis.¹⁹ Hospitalizations for dialysis patients are disproportionately costly and a significant driver of unnecessary costs of care.²⁰ Given that “crash” inpatient starts are potentially avoidable with adequate CKD management, outpatient starts are an important quality metric for effectiveness of nephrologist intervention in the pre-ESKD period.

CVC Removal

The rationale supporting the components of optimal dialysis emanate from quality measures included in the CMS Merit-Based Incentive Payment System (MIPS) program, recent process-based interventions in improving incident ESKD patient care, existing DaVita Home internal program goals, and the AAKH Executive Order. For patients who initiate hemodialysis with a CVC, prompt removal should be encouraged due to the increased risk of infectious complications, thrombosis, and risk of permanent central venous stenosis or occlusion.⁸ Furthermore, patients dialyzing with CVCs have a greater mortality risk.⁸ These factors are reflected in the MIPS 2019 Clinical Quality Measures #329 and #330, which discourage CVC use at the initiation of hemodialysis, and encourage removal of CVCs within 90 days of insertion.⁸

Home Conversion

Because nearly 40% of incident ESKD patients who present with an indication for kidney replacement therapy have no preceding CKD care, the opportunity for patients to be educated and prepare for home modalities is often limited.^{6,9,10} This results in the majority of ESKD patients beginning kidney replacement therapy on ICHD with a CVC and an increased risk of complications.^{6,9,10} ICHD to home dialysis conversions, even in patients with no contraindications to home modalities, is low.^{9,10} Process-based and programmatic focus on actively educating and encouraging conversion from ICHD to home modalities can be an effective means to improve home dialysis utilization.^{9,10}

References

- ¹ Mendum ML, et al. Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery, *J Am Soc Nephrol* 31: 602-614, February 2020 (ePub).
- ² National Quality Forum: NQF-Endorsed Measure 0018 Controlling High Blood Pressure. Available at: <https://www.qualityforum.org/Home.aspx>. Accessed March 26, 2020.
- ³ Merai R, Siegel C, Rakotz M, Basch P, Wright J, Wong B; DHSc., Thorpe P. CDC Grand Rounds: A Public Health Approach to Detect and Control Hypertension. *MMWR Morb Mortal Wkly Rep*. 2016 Nov 18;65(45):1261-1264.
- ⁵ National Quality Forum: NQF-Endorsed Measures for Renal Conditions, 2015. Available at: http://www.qualityforum.org/Publications/2015/12/Renal_Measures_Final_Report.aspx. Accessed March 3, 2020.
- ⁶ U.S. Department of Health and Human Services: Advancing American Kidney Health, 2019. Available at: <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed March 14, 2020.
- ⁷ Centers for Medicare and Medicaid: ESRD Vascular Access TEP Summary Report, April 22-23, 2015. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRD-Vascular-Access-TEP-Summary-Report.pdf>. Accessed March 12, 2020.
- ⁸ Centers for Medicare and Medicaid Quality Payment Program: Explore Measures & Activities, 2019. Available at: <https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2019#measures>. Accessed March 3, 2020.

EXTERNAL DISCUSSION DRAFT
April, 2022

⁹ Morfin JA, Yang A, Wang E, Schiller B. Transitional dialysis care units: A new approach to increase home dialysis modality uptake and patient outcomes. *Semin Dial.* 2018 Jan;31(1):82-87.

¹⁰ Bowman BT. Transitional Care Units: Greater Than the Sum of Their Parts. *Clin J Am Soc Nephrol.* 2019 May 7;14(5):765-767.

¹⁴ Tonelli M, Wiebe N, Knoll G, Bello A, Browne S, Jadhav D, Klarenbach S, Gill J. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *Am J Transplant.* 2011 Oct;11(10):2093-109. doi: 10.1111/j.1600-6143.2011.03686.x. Epub 2011 Aug 30. PubMed PMID: 21883901.

¹⁵ Purnell TS, Auguste P, Crews DC, Lamprea-Montealegre J, Olufade T, Greer R, Ephraim P, Sheu J, Kostecki D, Powe NR, Rabb H, Jaar B, Boulware LE. Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: a systematic review. *Am J Kidney Dis.* 2013 Nov;62(5):953-73. doi: 10.1053/j.ajkd.2013.03.022. Epub 2013 May 29. Review. PubMed PMID: 23725972; PubMed Central PMCID: PMC3809150.

¹⁶ Kasiske B, Israni A, Snyder J, Skeans M, Peng Y, Weinhandl E. A Simple Tool to Predict Outcomes After Kidney Transplant, AJKD, 2010-11-01Z, Volume 56, Issue 5, Pages 947-960.

¹⁷ [Chaudhary, Kunal, et al. Peritoneal Dialysis First: Rationale. Clinical Journal of the American Society of Nephrology, 2011 Feb;6\(2\):447-56.](#)

¹⁸ [Arif, Faisal M., et al. Early Mortality Associated with Inpatient versus Outpatient Hemodialysis Initiation in a Large Cohort of US Veterans with Incident End-Stage Renal Disease. Nephron, 2017; 137\(1\):15-22.](#)

¹⁹ [Bradbury, Brian D., et al. Predictors of Early Mortality among Incident US Hemodialysis Patients in the Dialysis Outcomes and Practice Patterns Study \(DOPPS\). Clinical Journal of the American Society of Nephrology, Jan 2007, 2 \(1\) 89-99.](#)

²⁰ Kshirsagar, Abhijit V., et al. Length of Stay and Costs for Hospitalized Hemodialysis Patients. *Journal of the American Society of Nephrology* Aug 2000, 11 (8) 1526-1533.

²¹ National Quality Forum (NQF). NQF Measure #1662: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy. Accessed at: <https://www.qualityforum.org/Home.aspx>

²² Mendum ML, Tummala P, Lentine KL, et al. Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery, *J Am Soc Nephrol* 31: February 2020 (ePub).

²³ Kidney Disease: Improving Global Outcomes (KDIGO) Blood Pressure Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Blood Pressure in Chronic Kidney Disease. *Kidney Int.* 2021 Mar;99(3S):S1-S87. Accessed at: https://kdigo.org/wp-content/uploads/2016/10/KDIGO_BP_Exec_Summary_final.pdf

²⁴ Kidney Disease: Improving Global Outcomes (KDIGO) Blood Pressure Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Blood Pressure in Chronic Kidney Disease. *Kidney Int.* 2021 Mar; Guideline Data Supplementary Tables S21-S22. Accessed at: https://kdigo.org/wp-content/uploads/2021/03/KDIGO_2021_BP_GL-Supplement.pdf

²⁵ Weir MR, Lakkis JI, Jaar B, Rocco MV, Choi MJ, Kramer HJ, Ku E. Use of Renin-Angiotensin System Blockade in Advanced CKD: An NKF-KDOQI Controversies Report. *Am J Kidney Dis* 2018 Dec;72(6):873-884.

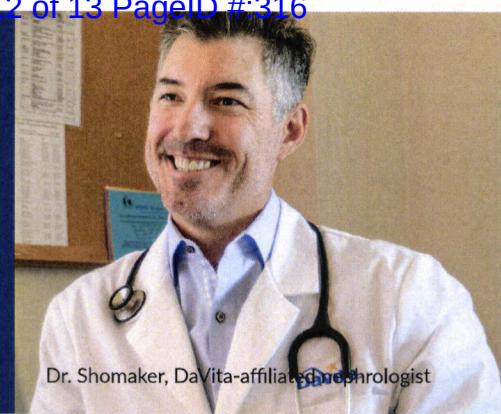
²⁶ Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney Int.* 2020 Oct;98(4S):S1-S115. Accessed at: <https://kdigo.org/wp-content/uploads/2020/10/KDIGO-2020-Diabetes-in-CKD-GL.pdf>

²⁷ Lunney M, Ruospo M, Natale P, et al. Pharmacological interventions for heart failure in people with chronic kidney disease. *Cochrane Database Syst Rev* 2020;2(2):CD012466.

²⁸ End-Stage Renal Disease Treatment Choices (ETC) Model Fact Sheet (Sept. 18, 2021). <https://www.cms.gov/newsroom/fact-sheets/end-stage-renal-disease-treatment-choices-etc-model-fact-sheet>

Exhibit 4

Nephrology Care Alliance Presents the Clinical Incentive Program



Dr. Shomaker, DaVita-affiliated nephrologist

Nephrology Care Alliance (NCA) has designed the Clinical Incentive Program (CIP) to incentivize nephrologists to achieve superior performance and clinical outcomes. The program is offered to nephrologists for program-eligible patients (members) through DaVita Integrated Kidney Care's (DaVita IKC) partnerships with health plans¹.

Program Eligibility

Patients are eligible based on the program terms² with each individual health plan where DaVita IKC has an applicable agreement. Nephrologists will be incentivized based on the following clinical metrics:

Home Start	Program-eligible patients new to dialysis whose first outpatient treatment is a home dialysis modality and who remains on a home dialysis modality for a period of not less than 90 days. Home dialysis modality includes either peritoneal dialysis (PD) or home hemodialysis (HHD). ³
Outpatient (In Center Hemodialysis) Start	Program-eligible patients new to dialysis who experience a planned start of kidney replacement therapy by initiating outpatient-in-center hemodialysis without preceding inpatient dialysis treatment. ⁴
AVF/AVG Only Start	Program-eligible patients new to dialysis who experience a planned start of kidney replacement therapy by initiating outpatient in-center hemodialysis via an AVF or AVG without a CVC in place.
CVC Removal	Program-eligible patients new to dialysis who initiates outpatient dialysis with either an active CVC or an inactive CVC and has transitioned to any access other than CVC within 90 days and had the CVC removed.
Home Conversion	Program-eligible patients who transfer from in center hemodialysis to a home dialysis modality for a period of not less than 90 days. Home dialysis modality includes either peritoneal dialysis (PD) or home hemodialysis (HHD). ⁵

Nephrologist Participation

To participate in this program:

- Enter into the CIP Agreement provided by NCA; and
- Complete DaVita compliance training within 90 days of the program's effective date.

Driving Impact

Your involvement is key to driving superior clinical outcomes, such as timely AVF/AVG placement and catheter removal to prevent infections. Educate your patients about the importance of home therapies and avoiding missed treatments to help them make better decisions about their health.

*Modality choice is made between the patient and their physician.

Member patient must remain in the CIP for no fewer than 90 days.

Clinical Incentive Payout Amounts

Home Start	\$2,800 per occurrence (one payment per patient)
Outpatient (In Center Hemodialysis) Start	\$1,200 per occurrence (one payment per patient)
AVF/AVG Only Start	\$1,000 per occurrence (one payment per patient)
CVC Removal	\$500 per occurrence (one payment per patient)
Home Conversion	\$400 per occurrence (one payment per patient)

Questions?

Contact contact@nephalliance.com.

1. DaVita Integrated Kidney Care and/or DaVita IKC is the trade name under which VillageHealth DM, LLC, and in some instances other teammates within DaVita Kidney Care, conducts business.
2. To review the full eligibility criteria for the program, please refer to the *NCA Clinical Incentive Program Agreement*.
3. Patient may have a CVC in place. Cannot be combined with Outpatient (In Center Hemodialysis) Start, AVF/AVG Only Start, or CVC Removal metrics.
4. Patient may have a CVC in place. Not applicable for Cigna program
5. Transfers between PD to HHD or HHD to PD are not eligible. Cannot be earned if Home Start metric already earned at start of dialysis.